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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,663	04/03/2000	Robert H. Adolfsen	MST-1980.2	4417

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EXAMINER

GORDON, BRIAN R

ART UNIT PAPER NUMBER

1743

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/541,663

Applicant(s)

ADOLFSEN ET AL.

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21, 2004 has been entered.

Response to Arguments

2. Applicant's arguments, see remarks, pages 8-9 filed Paper 15, with respect to the rejection(s) of claim(s) 52-57 under Kumar et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 52 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims as drafted are directed to the control of and adjustment of the

individual fluid segments as based upon a plurality of cycles. The specification on the other hand describes the method of adjusting the overall size (length, volume) of a test package by adjusting the first and final air segments in the individual test packages. The claim should be drafted in a method directed to the adjustment or the overall length of a test package by adjusting segments of the individual test package not a plurality of cycles.

The specification discloses a method in which adjustments are made during a single cycle. A cycle allows for the creation and adjustment of a single test package. Claim 1 defines a cycle as "beginning with the aspiration of a first air segment and ending with the aspiration of a final air segment". The broad interpretation of the claim would allow for any number of components beginning with an air segment and ending with an air segment to be considered as a cycle. For example, the aspiration of A1 to A2 may be considered as one cycle and the aspiration of A2 to A3 a second cycle (total of 3 segments per cycle). This would mean that a test package is formed by two cycles instead of one. The specification provides for a one-to-one ratio for which one cycle produces one test package.

The claim states "selectively aspirating liquid segments and air segment into a first fluid conduit in a plurality of cycles." Based on the fact that one cycle yields one test package, this step implies that more than one test package is aspirated into the first conduit. This would mean that there is no separation between test packages. Only one test package is disclosed as being present in the first conduit at one time. Based on the

above interpretation, the step of transferring also implies that a plurality of test packages are simultaneously transferred through the system.

5. Claims 52 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The fixed position of the detector is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The overall objective of the method is to create and analyze test packages of uniform length (applicant's remarks filed 1-21-04, pages 8-9). This is performed by having a device that comprises a bubble detector positioned at a fixed distance from the shear valve 40 (applicant's specification pages 16-18).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 52 and 58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how the method is performed. What constitutes a test package/cycle? As drafted the claim allows for a test package/cycle to be comprised of 3 components, while the specification (pages 2-3 and figures) appears to show that a test package/cycle is produced from a total of segments greater than 3.

It is unclear how many test packages/cycles are aspirated and processed in the device at one time.

As interpreted, it appears as if a plurality of cycles are simultaneously aspirated, as such it is unclear which final segment of which of the plurality of cycles is adjusted by closing the valve.

It is unclear where and when the step of detecting occurs. Which of the plurality of test packages/cycles is detected? Does detection occur at detector 80, 75, or 55?

It is unclear what final liquid/air segment interface is detected. As stated by applicant the last to enter the second conduit is the first to enter the third conduit. As such it appears as if the final segment becomes the first segment and the first segment becomes the final. Therefore it is unclear which final segment is detected and which final segment of which one of the plurality of cycles/test packages previously aspirated.

Applicant's method as disclosed within the specification appears to be establishing test packages of uniform length by adjusting the first and last segments of each package as needed via a shear valve and a detector placed at a fixed distance from the shear valve in the analytical line. The uniform length of the test packages appears to be established by using a first test package created in a first cycle. After the appropriate detection and adjustment is made to the first test package. The subsequent test package (created in a second cycle) may be adjusted accordingly and process is repeated a number of times of a number of test packages.

As to claim 58 it is unclear where the additional step occurs. Does it occur before the detecting step, after the detecting step, or after the stopping step of claim 52?

As to claim 60 it is unclear how two stopping steps occur. Claim 52 contain a stopping step that occurs after detecting and claim 60 provides for a second stopping step. How can the stopping step of claim 60 performed when claim 52 has previously established that the flow has been stopped? The step is redundant for if the flow has already been stop you cannot stop it again without restarting it.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg


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